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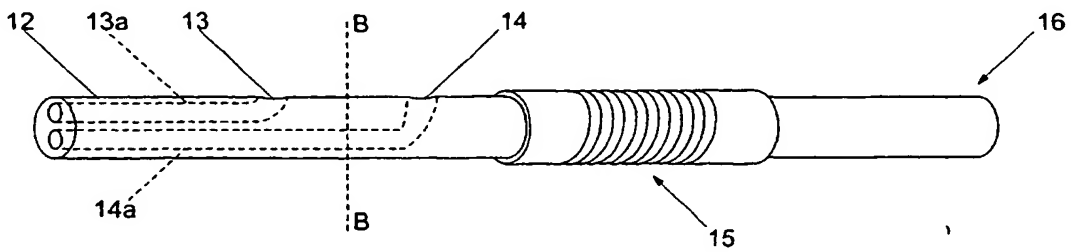

(57) Abstract: A catheter which includes means to measure local pressure at two or more points along the catheter body is described. The points are preferably located in two different pressure areas, more preferably across a valve in a vessel, organ or similar. The invention provides a method of gauging the positional location of a catheter in a blood vessel, organ or similar, either by the catheter having means to monitor the local pressure at two or more points along the catheter body, or means to measure pressure at a single point along the catheter body, which catheter is moveable to detect pressure differential measurements. The invention can be used to more accurately have knowledge of the position of a blood vessel, by means of a heat transfer device.

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IMPROVEMENTS RELATING TO CATHETER POSITIONING

The present invention relates to improvements for the positioning of catheters monitoring cardiac output data.

US 5509424 describes a catheter having a heat transfer device near its distal end for use in monitoring cardiac output within an artery. The apparatus determines cardiac output using selected features derived from a temperature difference signal based on measurement of average native blood temperature detected at a proximal temperature sensor from the temperature of a heating coil detected by a distal temperature sensor.

An important consideration in the use of such catheters is the importance of the location of the catheter and its heat transfer device. The main pulmonary artery of a human is generally only about five centimetres long,

and it is important to have the catheter positioned correctly in order to obtain the correct cardiac output (CO) information.

According to a non published study in 60 patients, the tip of a catheter, after normal flotation of the catheter into the main pulmonary artery (PA), could be between 0-8 cm in the left or right main branch of the PA. In the case of a catheter that relies on thermal dilution for the determination of cardiac output (CO), this positioning is acceptable. However, in the case of a catheter as described in US 5509424 which relies on the heat transfer principle for measurement of cardiac output, the position of the heat transfer element (HTD) is critical. If the HTD is located in a branch, then it will sense part of the flow giving a lower CO. Also if the HTD is near high turbulence, for example, near a valve or bifurcation, it would give higher CO. Hence it is important to control the position of HTD in order to improve the overall accuracy of CO determination.

One design of a cathater according to US 5509424 has a heat transfer device located at 7.5 cm from the distal tip (figure 1). This will ensure, based on the clinical study mentioned above, that the HTD would not be in a branch in 95% of the cases. However, based on one clinical study in 20 patients, there appeared to be a position influence in about 20-30% of the time (CO determined by heat transfer was significantly lower than CO determined by thermal dilution).

It is an object of the present invention to provide apparatus and method for a catheter for positional information.

According to one aspect of the present invention, there is provided a catheter which includes means to measure local pressure at two or more points along the catheter body.

The points are preferably located in two different pressure areas. The catheter preferably has a heat transfer device thereon, more preferably at or near its distal end.

The pressure measuring means may be fluid filled lumens which allow transmission of a pressure waveform to a pressure transducer which may be located outside the patient. Alternatively, pressure transduction means may be located at these points and the signal transmitted via electrical cables, fluid or fibre optic. The transduction means itself may be optical, semiconductor or some other means. The pressure measuring means may be identical or different. The transmission could pass along only one lumen.

The measuring means is preferably two or more pressure measuring devices such as diaphragms located along the length of the catheter body. The information from the different pressure measuring means can be referenced and calculated to indicate the position of the catheter, more particularly the catheter tip and any heat transfer device, in a blood vessel, organ or similar. The catheter could use an existing lumen or

includes an additional lumen to relay the information from the pressure measuring means to its proximal end.

According to a second aspect of the present invention, there is provided a method of gauging the positional location of a catheter in a blood vessel, organ or similar, the catheter having means to monitor the local pressure at two or more points along the catheter body, wherein the catheter is located along two different pressure areas, and the pressure differential measurements between the points in the two different areas is indicative of the location of the catheter.

The pressure detecting means of the present invention could be located across a valve in a blood vessel, organ or similar, eg the heart. In one embodiment of the present invention, one pressure detecting means is located in the pulmonary artery, and one pressure detecting means is located in an adjoining ventricle. The known different pressures of the blood in the pulmonary artery and the ventricle will create a pressure differential, and with knowledge of the artery pressure at the valve, the pressure differential information can be used to ensure that the catheter tip and heat transfer device is located where desired, eg whether the tip is in the atrium, the ventricle or in the pulmonary artery.

Typically a catheter according to the present invention will have means to locate pressure points so that the heat transfer device is in the centre of the main pulmonary artery.

According to a third aspect of the present invention, there is provided a method of gauging the positional location of a catheter in a blood vessel, organ or similar, the catheter having means to monitor the local pressure at a point along the catheter body, wherein the catheter is located in a first position in the vessel, organ or similar, and the local pressure measured, and the catheter is then moved to a second position in the vessel, organ or similar, and the local pressure measured, and the pressure measurements at the first and second locations are indicative of the location of the catheter.

This method would use only one pressure measuring means to detect the pressure waveforms. This allows minimising the size of a catheter for applications requiring the least possible outer diameter, for example in paediatric or neonatal cardiovascular system. The catheter would be moved forward until the indicative pressure waveform (measured by the pressure measuring means) changed indicating that the sensor had crossed a valve. The catheter could then be withdrawn until the valve is crossed again, to confirm the position. In this way any part of the catheter at fixed, known distances from the pressure sensing means can have location known relative to the position of the valve.

In a preferred embodiment, the catheter could have calibrated distance markings on its outer surface to assist in accurate determination of insertion and withdrawal distances.

According to a fourth aspect of the present invention there is provided a catheter which includes internal fluid piping whose fluid pressure is relatable to the general pressure of surrounding fluid external to the catheter, and at least one means to measure the fluid pressure in the internal piping.

The piping could directly use a portion of the fluid surrounding the catheter. Alternatively, the piping could relay information from an external pressure measuring means such as a diaphragm. The catheter preferably has a heat transfer device at or near its distal end.

Embodiments of the present invention are shown by way of example only in the accompanying diagrammatic drawings in which;

Figure 1 is a cross-sectional view through part of a first catheter according to the present invention;

Figure 2 is a cross-sectional view through a part of a second catheter according to the present invention; and

Figure 3 shows R.V. and PA traces provided by the catheter shown in Figure 2.

Figure 4 illustrates positioning of a Pulmonary Artery Catheter.

Referring to the drawings, Figure 1 is a cross sectional view of a section of a first catheter 2, having an internal fluid piping 4. Each end of the

piping 4 is covered by a diaphragm 6 aligned with the catheter outer wall 8. The piping 4 is filled with a fluid 10 such as a sterile saline solution or gel. The fluid should be non-toxic and bio-compatible.

In the middle of the piping 4 is a third diaphragm 11 connected to a pressure sensor (not shown) at the end of a lumen 14.

In use, this section of the catheter 2 is intended to be located across a differential pressure boundary (dashed line A-A) such as a heart ventricle valve, such that the pressure on one of the end diaphragms 6 of the piping 4 is different to that on the other. The different pressures on the end diaphragms 6 will result (through the internal fluid 10) in movement of the intermediate diaphragm 11, and movement of this diaphragm 11 can be measured by the pressure sensor.

With knowledge of the blood pressure at and around the heart, positive confirmation of the correct location of the catheter 2 can be provided by waiting for the desired pressure measurement to be sensed, confirming the location of the piping 4 across a valve. The precise position of the catheter tip and any associated heat transfer device can then be confirmed, also allowing correct determination of information relating to the heat transfer device.

Figure 2 shows a second catheter body 12 which has two measuring means 13, 14, with respective waveform transmissions means 13a, 14a. The dashed line BB indicates a pulmonary valve. The pressure waveform

trace measured at position 13 would be as shown in Figure 3; the waveform indicative of the right ventricle, R.V. Similarly, position 14 would show the waveform indicative of the pulmonary artery PA also shown in Figure 3. When the catheter 12 was so positioned as to give these respective waveforms the user would know the location of the pressure measuring means 13, 14 and hence the location of any other part of the catheter 12 which is a fixed distance along the catheter from those means. For example, if the distal tip 16 was 10 cm from point 14, then the user would know that the tip was approximately 10 cm from the pulmonary valve. Similarly for a heat transfer device 15, located for example 1cm from point 14.

Figure 4 illustrates positioning of a pulmonary artery catheter. The catheter (2) extends through the Superior Vena Cava (17), into the Right Atrium (18), into the Right Ventricle (19), into the Main Pulmonary Artery (20) and into the Right Pulmonary Branch (21). Use of pressure detecting means allows the heat transfer device to be positioned in the main pulmonary artery.

The present invention provides two approaches for actual clinical practice;

Approach 1

Provide a separate lumen for pressure monitoring. A current catheter according to US Patent No 5509424 has a cross section having 6 lumens described as follows:

The proximal injectate lumen terminates at a port located 30 cm from the distal tip. When the distal tip is located in the pulmonary artery, the proximal injectate port resides in the right atrium or vena cava, allowing for bolus cardiac output injections, right arterial pressure monitoring, blood sampling, or infusion of solutions.

The pulmonary artery (PA) distal infusion lumen terminates at the distal tip. During insertion, this port is used to monitor catheter location, via transitional pressure measurements. At full insertion, this port resides in the pulmonary artery, (allowing for pulmonary artery and pulmonary capillary wedge pressure measurements) or mixed venous blood sampling. This port also allows for infusion of solutions, pressure monitoring or blood sampling.

The distal and proximal thermistor lumens contain the electrical leads for the thermistors, which are positioned on the catheter surface, approximately 7.5 cm and 11 cm respectively from the distal tip. The thermistors are used to measure temperatures and in conjunction with the thermal coil, generate data used to calculate cardiac output. The distal thermistor is located immediately below the thermal coil.

The thermal coil lumen contains leads for the thermal coil, which is located 7.5 cm from the distal tip. The thermal coil generates heat

necessary for maintenance of a constant temperature differential between the proximal and distal thermistors. The energy required to maintain the fixed temperature differential, is used to calculate cardiac output continuously.

The balloon inflation lumen has a one-way stopcock at its proximal end and terminates in a latex balloon at the distal tip. When the catheter is properly positioned in the pulmonary artery, the balloon is inflated intermittently for the measurement of pulmonary artery wedge pressure. The balloon is inflated by a volume restricted syringe.

By combining the two thermistors and coil wires in one lumen, two lumens become available to be used for pressure monitoring.

In the first approach there is a slot (PC1) at 3cm below the heat transfer device (HTD), in one of the two vacated lumens, and another slot (PC2), in the second vacated lumen, at 2 cm above HTD. When the catheter is floated in place, the trace of PC1 should be PA waveform, and PC2 should be the right ventricular (RV) waveform if the HTD is located in mid PA. Manipulation of catheter position to achieve these traces ensures always locating the HTD in the right place.

Approach 2

Another approach would be to vacate only one lumen to use only one slot either below or above the HTD.

A. For example, if the pressure slot is located 3-4 cm below the HTD, the catheter can be advanced until this pressure slot shows a PA trace, then it is withdrawn slightly (e.g. 1 cm increments) until an RV trace is obtained. The HTD will then be in the main PA just after the pulmonic valve.

B. Or, the slot is placed 2 cm above the HTD. When the catheter is in place, withdraw catheter until an RV trace is observed, then advance 4 cm into PA. The HTD is then in the main PA above the pulmonic valve.

The present invention can be used to more accurately have knowledge of the position of the catheter in a blood vessel, organ or similar. Where the catheter includes a heat transfer device, the position of the heat transfer device can be more accurately calculated, and thus the nature of the heat measurements and associated cardiac information can be more accurately determined.

Particular applications for this invention include:

ensuring that a component is located in the pulmonary artery

ensuring that a component is located in the right ventricle

ensuring that the distal tip of a product is not more than a certain distance beyond the pulmonary valve.

The last point is relevant to any pulmonary artery catheter. It is important for the wellbeing of patients that the tip of any pulmonary artery catheter is not allowed too far beyond the pulmonary valve.

The novel apparatus and methods of the present invention could also be used in non-medical fields requiring accurate positioning of elongate tubing and the like in remote locations. Such fields include aeronautics, any fluid flow analysis, food and drink processing and monitoring, water and sewerage management, chemical engineering, fuel supply to engines, etc. Indeed, the present invention is also applicable to any device required to be placed beyond a one-way valve in a fluid flow situation, and/or any fluid flow situation which exhibits a pressure differential.

Claims

1. A catheter having a catheter body, wherein the body includes means to measure local pressure at two or more points along the catheter body.

2. A catheter as claimed in Claim 1 wherein the measuring means comprises two or more pressure measuring devices located along the length of the catheter body.

3. A catheter as claimed in Claim 2 wherein the pressure measuring devices are diaphragms.

4. A catheter as claimed in Claim 1 wherein the means comprises one or more fluid-filled lumens or piping.

5. A catheter as claimed in Claim 4 having one or more intermediate diaphragms across the or each lumen or piping.

6. A catheter as claimed in any one of the preceding Claims which includes a pressure transduction means.

7. A catheter as claimed in Claim 6 which includes signal transmission means able to transmit local pressure information from one or more points along the catheter body to the proximal end of the catheter.

8. A catheter as claimed in 7 wherein the signal is transmitted via one or more electrical cables, fluid or fibre optic.

9. A catheter as claimed in any one of the preceding Claims wherein pressure measurement information is passed along the catheter through one or more lumens in the catheter body.

10. A catheter as claimed in any one of the preceding Claims which includes one or more heat transfer devices.

11. A method of gauging the positional location of a catheter in a blood vessel, organ or similar, the catheter having means to monitor the local pressure at two or more points along the catheter body, wherein the catheter is located along two different pressure areas, and the pressure differential between the points in the two different areas is indicative of the location of the catheter.

12. A method as claimed in Claim 11 wherein the pressure monitoring means is located across a valve in a blood vessel organ or similar.

13. A method as claimed in Claim 12 wherein the pressure monitoring means is located across a valve in the heart.

14. A method of gauging the positional location of a catheter in a blood vessel, organ or similar, the

catheter having means to monitor the local pressure at a point along the catheter body, wherein the catheter is located in a first position in the vessel, organ or similar, and the local pressure measured, and the catheter is then moved to a second position in the vessel organ or similar, and the local pressure measured, and the pressure measurements at the first and second locations are indicative of the location of the catheter.

15. A method as claimed in Claim 14 for a paediatric or neo-natal catheter.

16. A method as claimed in Claim 14 or Claim 15 wherein the catheter is located in a first position on one side of a valve, and in the second position on the other side of the valve.

17. A method as claimed in any one of Claims 14-16 wherein the catheter has calibrated distance markings on its outer surface.

18. A catheter which includes internal fluid piping whose fluid pressure is relatable to the general pressure of surrounding fluid external to the catheter, and at lest one means to measure the fluid pressure in the internal piping.

19. A catheter as claimed in Claim 18 wherein the piping uses a portion of the fluid surrounding the catheter.

20. A catheter as claimed in Claim 18 wherein the piping relays information from an external pressure measuring means.

21. A catheter as claimed in Claim 20 wherein the external pressure measuring means is a diaphragm.

22. A catheter as claimed in any one of Claims 18-21 which includes a heat transfer device at or near its distal end.

23. A catheter as claimed in any one of Claims 1 to 10 and 18-22 for use in any one of: aeronautics, fluid flow analysis, food and drink processing and monitoring, water and sewage management, chemical engineering, fuel engine supply.

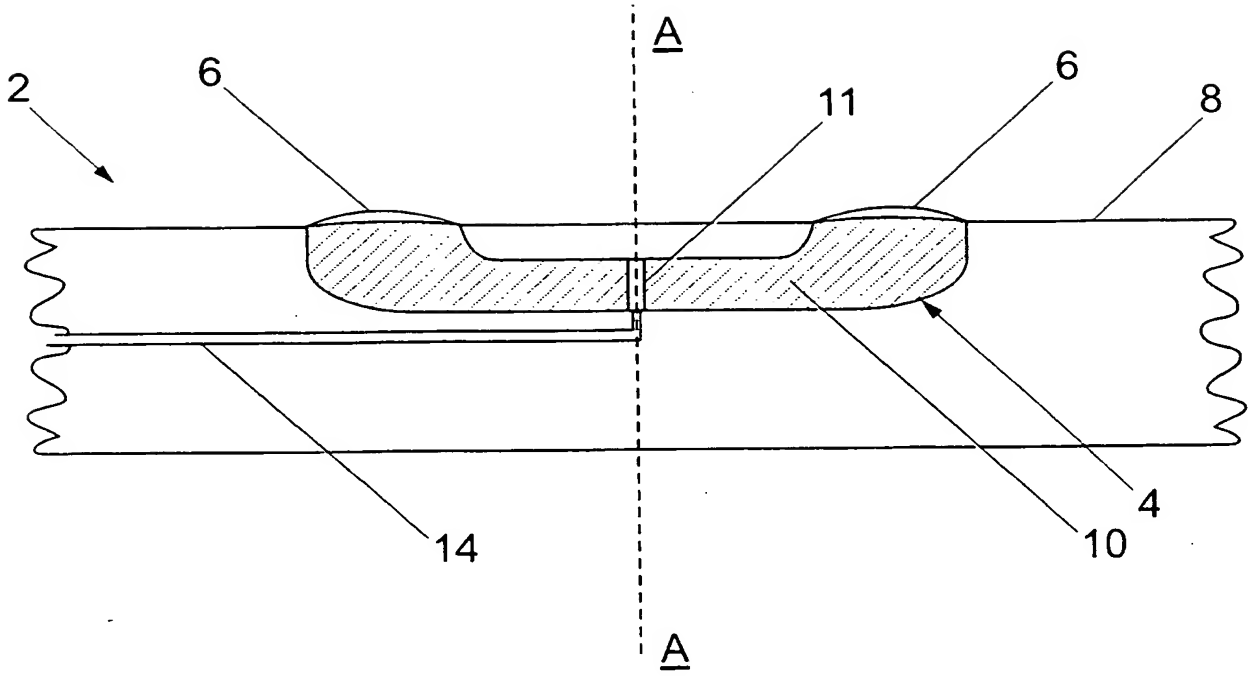

Fig. 1

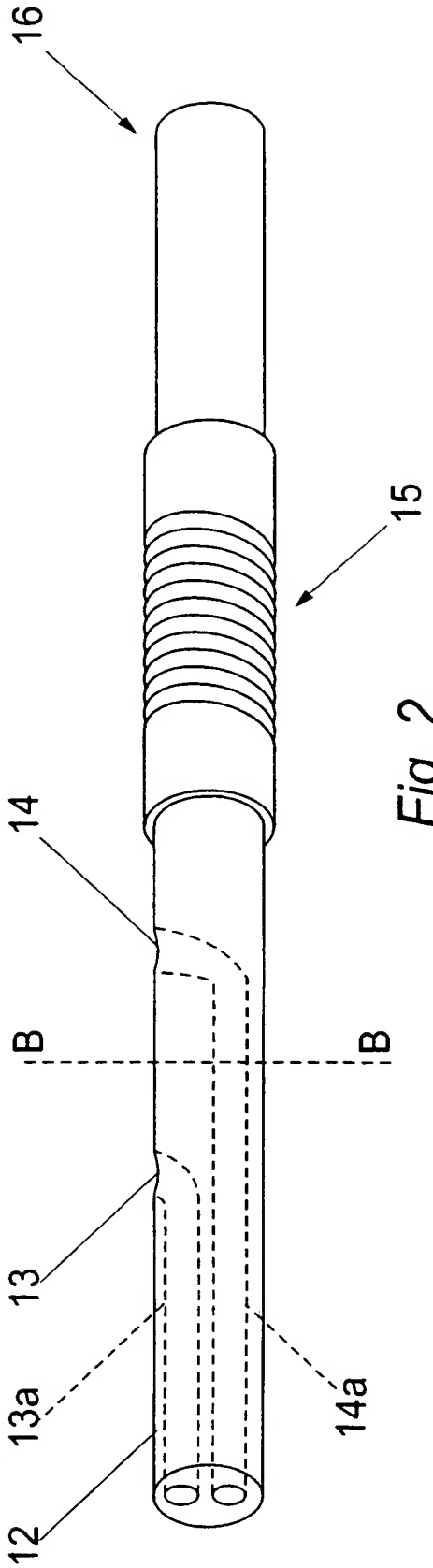

Fig. 2

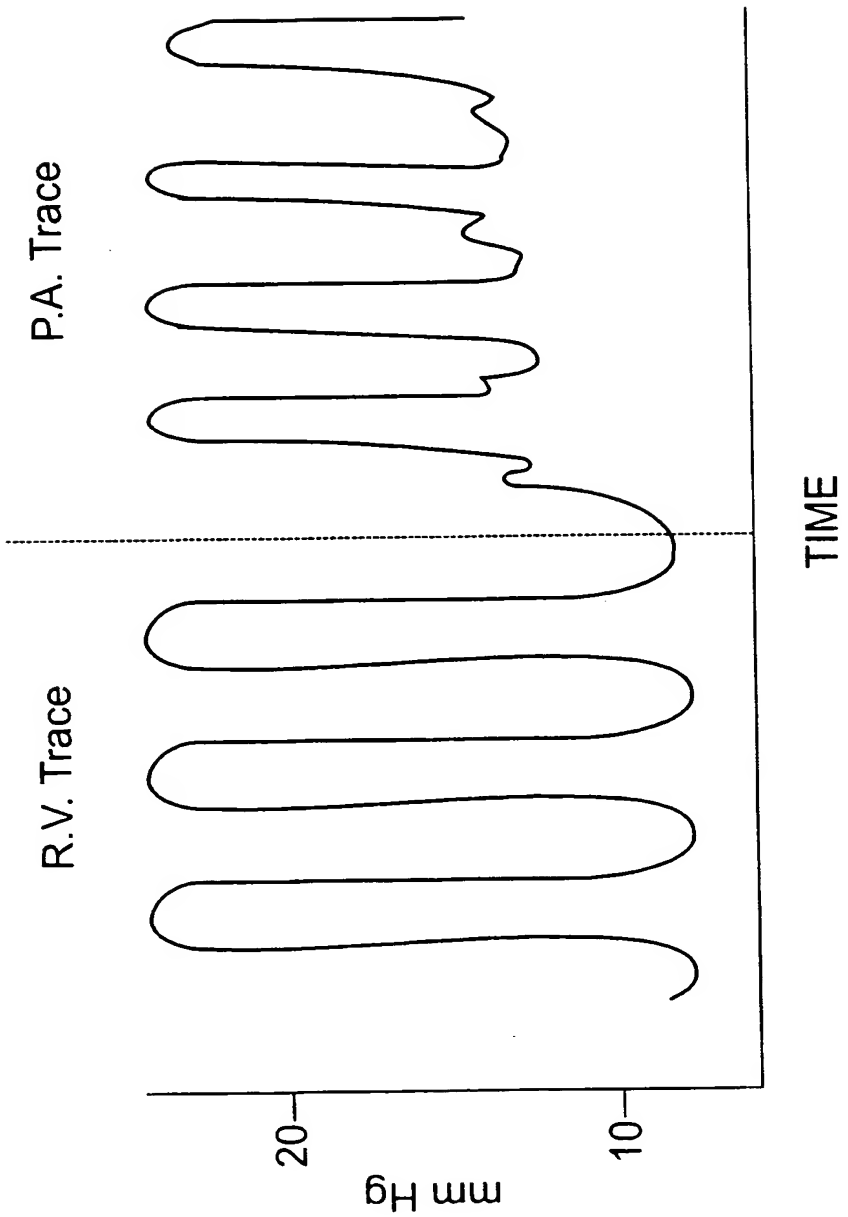

Fig. 3

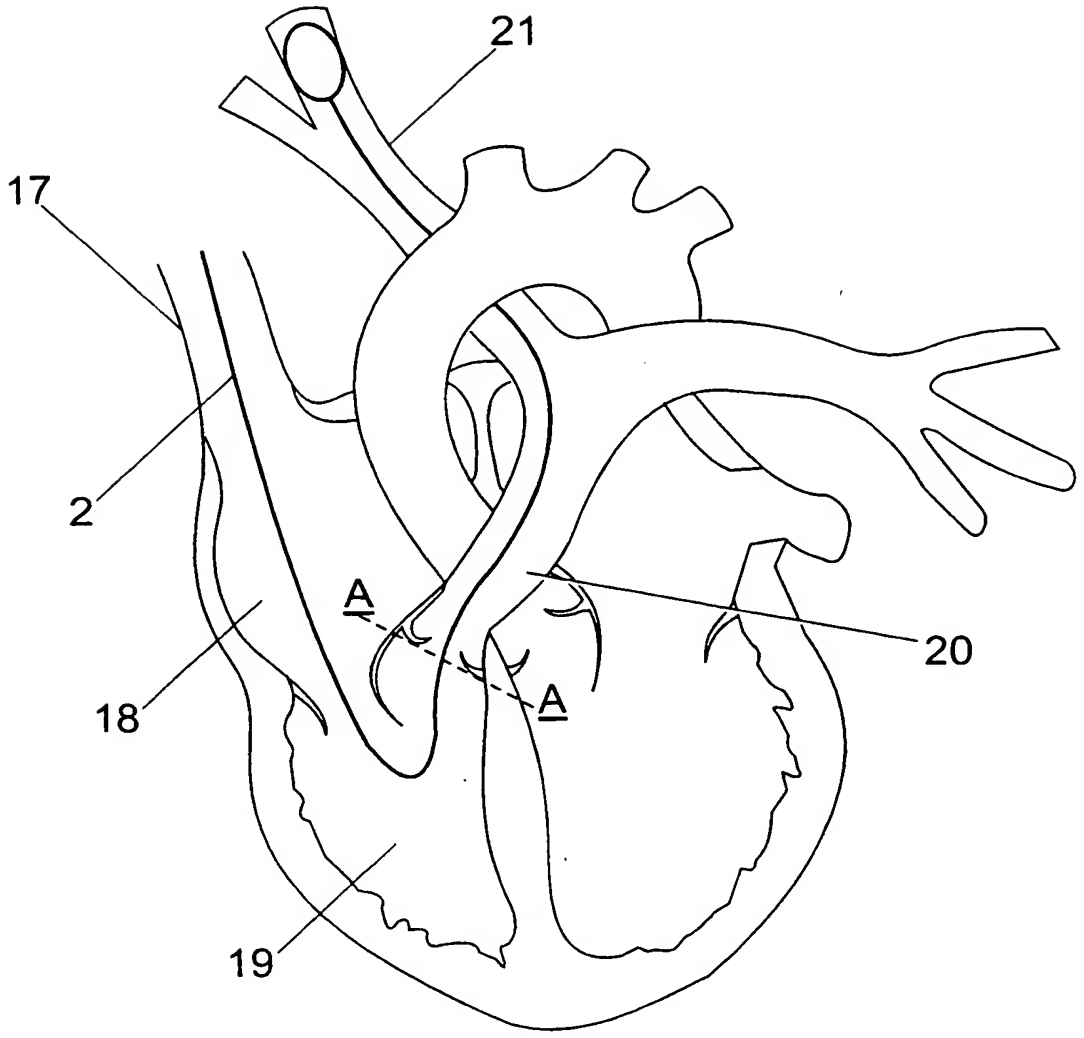

Fig. 4

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0215 A61B5/028

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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